IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	Scheele and Hildreth	Art Unit:	1648
Application No.:	10/625,090	Examiner:	E. M. Le
Filing Date:	July 22, 2003	Conf. No.:	8783
Title:	COMPOSITIONS AND METHODS FOR TREATING AND PREVENTING INFECTION		

MAIL STOP AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. §1.131

Sir:

I, Dr. George Scheele, co-inventor of the above-identified patent application do hereby declare and state that:

1. I am a co-inventor of the subject matter described and claimed in U.S. Patent Application Serial No. 10/625,090, filed on July 22, 2003, entitled "Compositions and Methods for Treating and Preventing Infection", which claims the benefit of priority to U.S. Provisional Patent Application No. 60/400,333, filed on July 22, 2002.

2. I am familiar with the prosecution history of U.S. Patent Application Serial No. 10/625,090.

3. I understand that the Examiner rejected claims 28, 31, 34-44, 49 and 53 under 35 U.S.C. §103(a) as allegedly unpatentable over Wallace et al. (U.S. Patent Application Publication 2003/00220294) in the Office Action mailed August 8, 2008.

4. I have reviewed Wallace et al. and am aware that it was filed on March 21, 2003 and claims priority to earlier filed U.S. Provisional Application No. 60/456,112, filed March 19, 2003, and U.S. Provisional Application No. 60/366,429, filed March 21, 2002, which is less than one year prior to July 22, 2002, the earliest priority date accorded to U.S. Patent Application Serial No. 10/625,090.

5. I respectfully submit that the claimed invention was conceived and reduced to practice in the United States prior to March 21, 2002, the earliest effective priority date of Wallace et al., as supported by the evidence which follows. All work papers provided herewith are true reproductions of the original documents.

6. Exhibit 1 is a copy of three consecutive laboratory notebook pages (pages 7-9 of the notebook) signed by myself, Dr. George Scheele, and witnessed by Mary Faulus. All dates and non-relevant subject matter on the laboratory notebook pages have been redacted. However, the dates were prior to March 21, 2002, the priority date of Wallace et al. Exhibit 1 provides the base discovery of using beta-cyclodextrin (2-OH-propyl-beta-cyclodextrin) for the reduction of viral load of envelope viruses, including herpes virus (types I and II) in the interstitial space of a mammal. For example, paragraph 2 of the second page of Exhibit 1 discusses the use of 2-OH-propyl-beta-cyclodextrin to reduce the viral load of herpes virus (types I and II). Exhibit 1 demonstrates that using beta-cyclodextrin (2-OH-propyl-beta-cyclodextrin) for the reduction of viral load of envelope viruses in a mammal, including herpes virus (types I and II), was obtained prior to the March 21, 2002 priority date of Wallace et al.

7. Exhibit 2 is a copy of three consecutive laboratory notebook pages (pages 10-12 of the notebook) signed by myself, Dr. George Scheele, and witnessed by Mary Krebiel. All dates and non-relevant subject matter on the laboratory notebook pages have been redacted. However, the dates were prior to March 21, 2002, the priority date of Wallace et al. Exhibit 2 provides the basis for the discovery that beta-cyclodextrin may be combined with antimicrobial agents (*e.g.*, antiviral agents) to achieve beneficial and synergistic effects in the reduction of viral load of envelope viruses (see, for example, paragraph 2 of page 1 of Exhibit 2) in a mammal.

8. Exhibit 3 is a copy of one laboratory notebook page (page 12 of the notebook) signed by myself, Dr. George Scheele. All dates and non-relevant subject matter on the laboratory notebook page have been redacted. However, the dates were prior to March 21, 2002, the priority date of Wallace et al. Exhibit 3 demonstrates that using beta-cyclodextrin (2-OH-propyl-beta-cyclodextrin) for the reduction of viral load of envelope viruses in a mammal was obtained prior to the March 21, 2002 priority date of Wallace et al.

9. Exhibit 4 is a copy of one laboratory notebook page (page 13 of the notebook) signed by myself, Dr. George Scheele, and witnessed by Mary Krebiel. All dates and non-relevant subject matter on the laboratory notebook page have been redacted. However, the dates were prior to March 21, 2002, the priority date of Wallace et al. Exhibit 4 provides the base discovery of using beta-cyclodextrin (2-OH-propyl-beta-cyclodextrin) to reduce the viral load of an envelope virus, including herpes virus (types I and II), in the interstitial space of a mammal. Exhibit 4 demonstrates that using beta-cyclodextrin (2-OH-propyl-beta-cyclodextrin) for the reduction of viral load of envelope viruses in a mammal, including herpes virus (types I and II) was obtained prior to the March 21, 2002 priority date of Wallace et al.

10. In summary, the Exhibits demonstrate that the presently claimed invention was conceived of and reduced to practice in the United States prior to March 21, 2002.

11. The undersigned further declares that all statements made herein of knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine, or imprisonment, or both under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

12-5-08
Date

Dr. George Scheele
Dr. George Scheele

On a theoretical basis I have made the following discoveries that relate to novels uses of 2-HP-BCD in cases of pathogen diseases:

(1) Viral sanitization (decontamination and treatment of viral particles on human and environmental surfaces. These formulations can be used on hands, wrists and arms of Professional health Care workers and can

be used in decontamination solutions such as alcohol and other antimicrobials to significantly improve the anti-infective nature of existing products or to provide entirely new sanitization products

(2) 2-HP-BCD may be particularly well suited as topical treatments of viral skin lesions, including Herpes Simplex viruses, types I (Labialis) and types II (Genitalis), Molluscum contagiosum, HIV skin lesions (Human Herpes virus type 8 or Kaposi's sarcoma), chicken pox, shingles etc.

(3) Protection and decontamination of human blood products and serum fractions, which may be contaminated with envelope viruses, such as those identified above.

(4) Early treatment as well as prevention of Influenza, Parainfluenza, Respiratory syncitial viruses that cause respiratory infections and still other envelope viruses that cause gastrointestinal diseases.

(5) Treatment of pox viruses including smallpox. Treatment and prevention.

(6) 2-HP-BCD may be used in the development of vaccines.

(7) 2-HP-BCD may be used in the corporeal or extracorporeal treatment of HIV, Hepatitis B, C, D, Influenza

These discoveries will be incorporated and developed in a confidential business plan, probably for a new business entity and developed into provisional patent applications. They are hereby recorded to provide priority dates for the discoveries.

Mary Faulus George A. Schrella

2-HP-BCD has the interesting property of an amphoteric toroid, with hydrophilic properties on the outside and hydrophobic properties on the inside surface of the toroid or cup structure.

The discovery reported herewith is to use 2-HPBCD in combination with hydrophobic agents, e.g. detergents, other amphoterics, anti microbial substances and the like to achieve the following novel, beneficial and synergistic effects:

a) Detergents such as monoxynyl 9 (n-9), Sodium dodecyl sulfate etc are toxic to microorganisms but are also toxic to host cells. At the appropriate ratio of detergents and 2-HP-BCD the cyclodextrin will mask the toxicity of the detergents. As the 2-HP-BCD extracts cholesterol from the pathogen an exchange reaction can be envisioned whereby the detergent enters the membrane of the pathogen. Thus, one will

obtain a synergistic effect of both the 2-HP-BCD (extraction of cholesterol from the membranes of envelope viruses and other pathogens) and the detergent/amphoteric drug thus obtaining a combined effect and a synergistic effect as well. At the same time the toxicity of the detergent and/or amphoteric active may be reduced or abolished.

b) Another example follows. Benzalkonium Chloride is an effective antifungal agent yet it has toxic effects on human host cells. According to the masking phenomenon described above in (a) 2-HP-BCD may mask the toxicity of benzalkonium chloride and yet make this antimicrobial available for deleterious effects on fungi and other pathogens. Other agents with hydrophobic structures may interact with 2-HP-BCD in a similar and beneficial manner.

Claims Overleaf

Mary Kubica George O. Schiele

The discoveries and ideas concerning using 2-HP-BCD both in the treatment and prevention of envelope viruses as well as non-envelope viruses and non-viral pathogens have been recorded and further developed in the confidential business plan written over the Christmas Holidays in

George O. Schiele

Mary Kubica George C. Schiele

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George C. Schiele

This entry will indicate the following:

I called "Dr. a dermatologist at SMDC in Duluth Minnesota to speak, in confidential terms, about the potential for commercial development of 2-OH propyl-BCD for prevention and treatment of Herpes, types I and II, skin lesions, Influenza, Hepatitis B & C, HIV and pox viruses. Dr. expressed a positive interest in these applications and as a dermatologist expressed particular interest in the potential use of 2-HP-BCD for treatment and prevention of Herpes type I and Herpes type II skin lesions. I reported this positive response back to and indicated that he would help to make contacts in NYC related to raising funds to develop products for these commercial applications.

Mary Kidder

George A. Schuler